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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|--------------------------------|-------------------------|----------------------|---------------------|------------------|
| 10/631,953 | 07/31/2003 | Bozidar Ferck-Petric | P8856.04 | 1782 |
| ²⁷⁵⁸¹ MEDTRONIC, | 7590 09/19/2007 INC. | EXAMINER | | |
| 710 MEDTRO | NIC PARKWAY NE | RAJAN, KAI | | |
| MINNEAPOLI | S, MN 55432-9924 | | ART UNIT | PAPER NUMBER |
| | | | 3736 | |
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| | | | MAIL DATE | DELIVERY MODE |
| | | | 09/19/2007 | PAPER |

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

| · . | Application No. | Applicant(s) |
|--|---|---|
| · · · · · · · · · · · · · · · · · · · | 10/631,953 | FEREK-PETRIC ET AL. |
| Office Action Summary | Examiner | Art Unit |
| , | Kai Rajan | 3736 |
| The MAILING DATE of this communication Period for Reply | appears on the cover sheet wi | th the correspondence address |
| A SHORTENED STATUTORY PERIOD FOR REWHICHEVER IS LONGER, FROM THE MAILING - Extensions of time may be available under the provisions of 37 CF after SIX (6) MONTHS from the mailing date of this communication. If NO period for reply is specified above, the maximum statutory period for reply within the set or extended period for reply will, by some any reply received by the Office later than three months after the rearned patent term adjustment. See 37 CFR 1.704(b). | G DATE OF THIS COMMUNION R 1.136(a). In no event, however, may a r n. eriod will apply and will expire SIX (6) MON tatute, cause the application to become AE | CATION. reply be timely filed ITHS from the mailing date of this communication. BANDONED (35 U.S.C. § 133). |
| Status | | |
| 1) Responsive to communication(s) filed on 2 | 24 August 2007. | · |
| · · · · · · · · · · · · · · · · · · · | This action is non-final. | |
| 3) Since this application is in condition for all closed in accordance with the practice und | • | • |
| Disposition of Claims | | |
| 4) Claim(s) 1 - 6 is/are pending in the applica 4a) Of the above claim(s) 7 - 40 is/are with 5) Claim(s) is/are allowed. 6) Claim(s) 1 - 6 is/are rejected. 7) Claim(s) is/are objected to. 8) Claim(s) are subject to restriction and continuous claim(s) are subject to restriction claim(s) | drawn from consideration. | |
| Application Papers | | |
| 9) The specification is objected to by the Exar 10) The drawing(s) filed on is/are: a) Applicant may not request that any objection to Replacement drawing sheet(s) including the co | accepted or b) objected to the drawing(s) be held in abeyar | nce. See 37 CFR 1.85(a). |
| 11)☐ The oath or declaration is objected to by th | e Examiner. Note the attached | Office Action or form PTO-152. |
| Priority under 35 U.S.C. § 119 | | |
| 12) Acknowledgment is made of a claim for formal All b) Some * c) None of: 1. Certified copies of the priority document of the priority document of the priority document of the certified copies of the application from the International But * See the attached detailed Office action for a second of the priority document of the p | nents have been received. nents have been received in A priority documents have been ireau (PCT Rule 17.2(a)). | pplication No received in this National Stage |
| | | |
| Attachment(s) | | |
| 1) Motice of References Cited (PTO-892) | 4) Interview S | Summary (PTO-413) |
| Notice of Draftsperson's Patent Drawing Review (PTO-948 Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date 2/14/2005 & 5/16/2005. | Paper No(s | s)/Mail Date nformal Patent Application |

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DETAILED ACTION

Election/Restrictions

Claims 7 – 40 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention, there being no allowable generic or linking claim.

Election was made without traverse in the reply filed on August 24, 2007.

Double Patenting

Claims 1 and 2 of this application conflict with claim 1 of Application No. 09/475,709.

37 CFR 1.78(b) provides that when two or more applications filed by the same applicant contain conflicting claims, elimination of such claims from all but one application may be required in the absence of good and sufficient reason for their retention during pendency in more than one application. Applicant is required to either cancel the conflicting claims from all but one application or maintain a clear line of demarcation between the applications. See MPEP § 822.

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The

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filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 1 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 1 of prior U.S. Patent No. 09/475,709. This is a double patenting rejection.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

Claims 1 – 6 are rejected under 35 U.S.C. 102(e) as being anticipated by Scheiner et al. U.S. Patent No. 6,361,522.

1. An interactive remote drug dose and physiologic response monitoring system in a patient wherein at least one IMD is adapted to communicate with a drug delivery device, the monitoring system comprising:

a drug delivery device (Column 2 lines 9 - 22); and

an IMD in wireless communications with the drug delivery device (Column 2 lines 35 – 42),

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wherein the IMD is implanted in a patient under a prescriptive regimen to take a drug from the drug delivery device and the IMD monitors the patient's physiological signs for compliance with a prescriptive regimen, and checks drug interaction in the patient (Column 4 lines 24 - 52).

- 2. The system of claim 1, wherein the delivery device is chosen from one of the following: a pill box, a transdermal patch, a IV, an inhaler, an oral medicament dispenser, a subcutaneous implant, a drug pump, or a transcutaneous application (Column 2 lines 9-22).
- 3. A drug delivery monitoring system comprising:
 means for monitoring parameters of a drug delivery device (Column 4 lines 24 52);
 means for communicating the monitored parameters with an IMD (Column 4 lines 24 52);

means for processing the monitored parameters (Column 4 lines 24 - 52); means for controlling the drug delivery device based on the processing of the sensed parameters (Column 4 lines 24 - 52).

4. The system of claim 3, further comprising:

means for sensing physiological parameters through the IMD (Column 4 lines 24 – 52);

means for processing the sensed physiological parameters relative to a drug delivered by
the drug delivery system (Column 4 lines 24 – 52); and

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means for controlling the drug delivery system in response to the processing of the sensed physiological parameters (Column 4 lines 24 - 52).

- 5. The system of claim 3, further comprising means for controlling a therapy delivered by the IMD based upon the means for processing the monitored parameters (Column 4 lines 24 52).
 - 6. An implantable medical device comprising:

a microprocessor for controlling cardiac therapy parameters (Column 2 line 62 – column 3 line 34);

a lead for delivering electrical stimulation to cardiac tissue (Column 2 line 62 – column 3 line 34); and

a telemetry unit for receiving information from a drug delivery device, the information identifying whether an expected drug therapy is delivered, wherein the microprocessor varies the cardiac therapy delivery through the lead based upon the information (Column 4 lines 24 - 52).

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kai Rajan whose telephone number is 571-272-3077. The examiner can normally be reached on Monday - Friday 9:00AM to 4:00PM.

Information regarding the status of an application may be obtained from the Patent

Application Information Retrieval (PAIR) system. Status information for published applications

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may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KR September 5, 2007 Michael Astorino